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Home versus clinic pelvic floor exercises for women with urine leakage

Submission date
26/01/2026

Recruitment status
No longer recruiting

Registration date
03/02/2026

Overall study status
Completed

Last Edited
03/02/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many women experience urine leakage during everyday activities such as coughing, sneezing, laughing, or exercising. This condition is known as stress urinary incontinence. It happens when the pelvic floor muscles, which support the bladder and help control urine flow, become weak. Pelvic floor muscle exercises are commonly recommended as a first treatment. These exercises help strengthen the pelvic floor muscles and can reduce or stop urine leakage. Pelvic floor exercises can be done under the supervision of a physiotherapist in a clinic or independently at home.
Clinic-based exercises may work well, but regular hospital visits can be difficult for some women because of work commitments, childcare responsibilities, travel distance, or cost. Home-based exercises are more convenient, but some women may not be sure if they are performing the exercises correctly.
Vaginal weights (also called vaginal cones) are small devices that are placed into the vagina during exercise. They provide physical feedback that helps women identify and contract the correct muscles. This may help women perform pelvic floor exercises more effectively at home.
The aim of this study is to compare two ways of performing pelvic floor muscle exercises in women with urine leakage:
1. Exercises performed at home using vaginal weights, and
2. Exercises performed under the supervision of a physiotherapist in a clinic.
The study aims to find out whether home-based exercises using vaginal weights are acceptable to women and whether they work as well as supervised clinic-based exercises in improving urine leakage and pelvic floor muscle strength.

Who can participate?
Women aged between 18 and 70 years who have stress-related urine leakage

What does the study involve?
Women who agree to take part will be randomly assigned to one of two groups. Random assignment means that each participant has an equal chance of being placed in either group.
One group will perform pelvic floor muscle exercises at home using vaginal weights. These participants will attend a training session where a clinician explains how to identify and correctly contract the pelvic floor muscles. They will receive written instructions and a set of vaginal

weights. The weight used will be chosen based on what is suitable for each individual. Participants will perform the exercises at home for 2 months and will record their exercise sessions in a diary.
The second group will perform pelvic floor muscle exercises under the supervision of a physiotherapist in a clinic. These participants will attend regular clinic sessions over 2 months and perform pelvic floor exercises following standard care practice.
All participants will have assessments before starting the exercises and again after 2 months. These assessments include:
1. A short questionnaire about urinary symptoms
2. A simple test to measure how much urine leaks over 1 hour
3. An examination to assess pelvic floor muscle strength
4. A question about how satisfied they are with their assigned exercise method

What are the possible benefits and risks of participating?
Participants may benefit from improved bladder control, reduced urine leakage, and stronger pelvic floor muscles. They may also gain a better understanding of how to perform pelvic floor exercises correctly, which could help them continue exercising after the study ends.
The risks of taking part are low. Some women may feel mild discomfort when using vaginal weights or during pelvic examination. Temporary muscle soreness or vaginal discomfort may occur, especially when starting the exercises. There is a small risk of minor irritation. Participants can stop the exercise at any time if they feel uncomfortable and can contact the research team if they have concerns.

Where is the study run from?
The study is run from the University Malaya Medical Centre (UMMC) in Kuala Lumpur, Malaysia. Participants are recruited from the Gynaecology clinic and the Women's Health physiotherapy clinic at UMMC.

When is the study starting and how long is it expected to run for?
February 2026 to August 2026

Who is funding the study?
University Malaya Medical Centre (Malaysia)

Who is the main contact?
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Study information

Scientific Title
A randomised comparative trial of self-performed pelvic floor muscle exercise (PFME) with vaginal cone vs supervised pelvic floor muscle exercise in women with stress urinary incontinence

Acronym
CONE-PFME

Study objectives
To compare the patient satisfaction and effectiveness of self-performed PFME using vaginal cones versus supervised PFME in improving urinary symptoms among women with stress urinary incontinence.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/12/2025, Medical Research Ethics Committee, University Malaya Medical Centre (Universiti Malaya Medical Centre Jln Professor Diraja Ungku Aziz Seksyen 13 50603 Petaling Jaya, Kuala Lumpur, 50603, Malaysia; +60 (0)3 7949 8473; iresearch@ummc.edu.my), ref: 202565-15143

Primary study design

Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Stress urinary incontinence

Interventions
This study is a prospective, randomised comparative interventional trial involving women diagnosed with stress urinary incontinence. Eligible participants are recruited from gynaecology and women's health physiotherapy clinics after providing written informed consent. Participants are randomly allocated into one of two study arms using a sequentially numbered, opaque, sealed envelope system to ensure allocation concealment.

Intervention arm: Self-performed pelvic floor muscle exercise (PFME) with vaginal cone
Participants receive a single structured training session conducted by a clinician. This session includes verbal instruction and written educational materials on identifying and correctly contracting pelvic floor muscles. Vaginal cones are introduced as a biofeedback tool. An individual starting cone weight is determined for each participant based on the maximum weight that cannot be held comfortably for 10 minutes. Three progressively heavier cones are prescribed.

Participants perform PFME at home for a total duration of 90–120 minutes per week for 2 months. Exercises may be completed in continuous or divided sessions. Each session begins with vaginal cone use for up to 15 minutes, followed by continued pelvic floor muscle exercises with or without the cone. Participants record exercise frequency and duration in an exercise diary.

Control arm: Supervised pelvic floor muscle exercise (PFME)
Participants attend supervised pelvic floor muscle exercise sessions with a physiotherapist every 2 weeks for a period of 2 months, in accordance with standard clinical practice. Exercises include fast and slow pelvic floor muscle contractions and adjunct core muscle exercises. Exercise performance and adherence are monitored and documented by the physiotherapist.

Baseline assessments are conducted prior to intervention and include a 1-hour pad test, Urinary Distress Inventory-6 (UDI-6) questionnaire, and pelvic floor muscle strength assessment using the Modified Oxford Score. All assessments are repeated at two months following completion of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Patient satisfaction with allocated pelvic floor muscle exercise intervention measured using a Verbal Numeric Rating Scale (VNRS) at 2 months after completion of the intervention

Key secondary outcome(s)
1. Objective urine leakage measured using a standardised 1-hour pad test according to International Continence Society guidelines at baseline and 2 months after completion of the intervention

2. Urinary symptom severity measured using the Urinary Distress Inventory-6 (UDI-6) at at baseline and 2 months after completion of the intervention

3. Pelvic floor muscle strength measured using digital vaginal examination and graded using the Modified Oxford Scale (score 0–5) at baseline and 2 months after completion of the intervention

Completion date
30/08/2026

Eligibility

Key inclusion criteria
1. Women aged 18 to 70 years
2. Diagnosed with stress urinary incontinence
3. Able to understand instructions and willing to perform pelvic floor muscle exercises
4. Willing to attend scheduled follow-up sessions

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Current urinary tract infection
2. Pelvic organ prolapse (stage 3 or above)
3. Previous pelvic floor surgery or incontinence surgery
4. Neurological conditions affecting bladder or pelvic floor function (e.g., spinal cord injury, multiple sclerosis)
5. Contraindications to using a vaginal device (e.g., active vaginal infection, recent vaginal surgery)

Date of first enrolment
01/02/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Malaysia

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type

Funder Name
University Malaya Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available